DECLARATION OF LARRY D. SASICH

1. My name is Larry D. Sasich, PharmD, MPH, FASHP. I am over the age of twenty-one and competent to testify to the truth of the matters contained herein. The factual statements I make in this declaration are true and correct to the best of my knowledge and experience. The opinions I express in this statement are made to a reasonable degree of scientific certainty.

2. I am a Consultant specializing in drug safety and efficacy issues. My background, experience and qualifications, in part, include:

    a. Serving as Chairperson of the Department of Pharmacy Practice at the LECOM School of Pharmacy in Erie, Pennsylvania, from 2007 to 2009.

    b. Serving as a consultant to Public Citizen Health Research Group, Washington, D.C.

    c. Serving as a Consumer Representative on the Science Board of Food and Drug Administration's, an advisory committee to the FDA Commissioner.

    d. Serving as a consultant to the Saudi Food and Drug Authority, Riyadh, Saudi Arabia.

3. I have a Masters in Public Health, with an emphasis in biostatistics and epidemiology from the George Washington University, and a Doctorate of Pharmacy from University of the Pacific. I have completed a residency in nuclear pharmacy at the University of New Mexico. I have also been elected a Fellow in the American Society of Health-System Pharmacists (FASHP). I have also authored publications and/or presented analysis on drug safety issues. A complete list of my publications and presentations are listed in my Curriculum Vitae, which is appended to this Declaration.

4. Counsel representing Mr. Russell Bucklew, a Missouri condemned prisoner, scheduled for execution on May 21, 2014 requested my

comments on drugs used in Missouri executions including whether the use of compounded pentobarbital sodium posed specific risks to Russell Bucklew during an execution under Missouri's protocol.

5. Mr. Bucklew suffers from a condition known as cavernous hemangioma, which is a type of blood vessel malformation that features weakened, distended vessels that can readily hemorrhage. Based on Mr. Bucklew's medical records, I understand that Mr. Bucklew bleeds daily or almost daily and thus he can be classified as an individual at a high risk of bleeding.

Methylene Blue

6. As part of my review in this case, I reviewed Missouri's lethal injection protocol as well as the Missouri Simulation Training for Execution Team Members dated October 30, 2013.

7. Based on these materials, it appears that Mr. Bucklew will receive an injection containing the drug methylene blue approximately 30 minutes before the injection of the lethal drug. The dose of methylene blue is not stated in the Missouri Simulation Training document.

8. One of the uses of methylene blue is as a vasopressor or blood pressure increasing agent in a condition known as vasoplegic syndrome. A type of statistical summary known as a meta-analysis found that methylene blue raises a person's average blood pressure by 6.93 mmHg and that an increase as high as 12.18 mmHg cannot be ruled out.[1]

9. An increase in blood pressure could result in Mr. Bucklew experiencing a profound hemorrhage during an execution.

10. Methylene blue has been used in patients with cavernous hemangioma in clinical studies to visualize blood flow. However,

[1] Pasin L, Umbrello M, Greco T, et al. Methylene blue as a vasopressor: a meta-analysis of

to the best of my knowledge, it has not been used in patients with a high risk of bleeding such as Mr. Bucklew.

11. It is highly likely that the use of methylene blue with Mr. Bucklew will result in significant hemorrhaging, thereby causing profound pain and extreme discomfort before the lethal dose of pentobarbital sodium is injected.

Pharmacy Compounded Pentobarbital Sodium

12. Recognition of the serious quality problems with pharmacy-compounded drugs peaked during the New England Compounding Center scandal that caused a nationwide epidemic of fungal meningitis resulting in over 700 cases and 64 deaths in 2012. There have been subsequent smaller epidemics of serious injury and death resulting from the use of pharmacy compounded injectable drugs.

13. Pharmacy compounded drugs are not approved by the FDA for any purpose.

14. In pharmacy compounded drugs the exact substances, contaminates and their amounts are unknown. The use of pharmacy compounded injectable drugs has had, in many cases, adverse effects on the individuals receiving these drugs. The unknown contaminates contained in pharmacy compounded drugs are highly likely to increase the risk that Mr. Bucklew will hemorrhage during the execution.

15. The oversight of compounding pharmacies by state boards of pharmacy and the FDA has been inadequate. Pharmacy compounded drugs are not tested for safety and efficacy and are not produced in facilities meeting federal Good Manufacturing Practice (GMP) guidelines that insure product quality, potency, stability, and are free of contamination.

16. Further, it is my understanding that the State of Missouri has failed to provide any information about whether the compounded pentobarbital that it uses in executions is tested to ensure that it

meets any standards for safety, potency and purity.

17. The contract testing laboratories typically used by compounding pharmacies are unregulated, and these laboratories have tested and passed pharmacy-compounded drugs that have resulted in harm and in some cases death. Moreover, there is no information to suggest that Missouri has even used one of these laboratories to test the execution drugs.

18. Although FDA-approved pentobarbital sodium does not appear to have a deleterious effect on blood pressure in FDA-approved therapeutic doses, that generalization does not apply to the use of compounded pentobarbital in lethal injection. In lethal injection, the drugs used are not FDA-approved, and they are used in amounts that have never been reviewed or approved by the FDA. Further, there is no way to conduct an ethical clinical trial to assess the effect on blood pressure in which lethal doses of pentobarbital sodium are administered.

19. The use of pharmacy-compounded pentobarbital in the execution of Mr. Bucklew poses grave risks. Compounded drugs are of unknown safety, potency and purity, and such unknown substances pose a greater risk to those who already suffer from serious medical conditions, such as Mr. Bucklew. The risks to Mr. Bucklew are substantial and include the presence of cross contaminates such as anticoagulants (blood thinners) and other drugs that have an effect on blood clotting that increase his risk of hemorrhaging. And allergens that can cause immediate severe allergic reactions, improperly adjusted pH (acidity), contamination with live bacteria or fungi, and bacterial endotoxins. There is also the possibility with any pharmacy-compounded drug that the product is sub potent or super potent.

20. In conclusion, Missouri's lethal injection protocol poses a significant risk that Mr. Bucklew will suffer extreme pain and discomfort during the execution, based on the great likelihood that the use of methylene blue will cause a spike in his blood pressure, thus putting him at great risk of hemorrhaging. Mr. Bucklew is also likely to suffer great pain and discomfort because

his medical condition places him at a high risk of bleeding if he is injected with pharmacy compounded pentobarbital sodium containing unknown contaminates that can increase his risk of hemorrhaging.

I declare under pain and penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Larry D. Sasich, PharmD, MPH, FASHP

May 8, 2014
Date